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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/565,497

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Naoyuki Yamamoto

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EXAMINER

KOSAR, AARON J

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/565,497	Applicant(s) YAMAMOTO ET AL.	
	Examiner AARON J. KOSAR	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-13,15 and 16 is/are pending in the application.
- 4a) Of the above claim(s) 5-13 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/07/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Amendment

Applicant's amendment and argument filed October 7, 2009, in response to the non-final rejection, are acknowledged and have been fully considered. Any rejection and/or objection of record not specifically addressed is herein withdrawn.

Applicant has amended the claims by canceling claims 2 and 14 and introducing new claims 15 and 16 which have been placed in groups II and I, respectively. Claims 1, 3-13, 15, and 16 are pending of which claims 5-13 and 15 are/remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1, 3, 4, and 16 have been examined on the merits.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 4, and 16 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Byun et al (2001, J. Agric. Food Chem., 49(4), 2061-2063.).

A casein hydrolysate, comprising free amino acids (a.a.) and peptides having an average a.a. of not longer than 2.1 a.a. residues, said peptides comprising indigestible peptides consisting of Xaa-Pro and Xaa-Pro-Pro, is claimed

Byun teaches a casein hydrolysate having an average of less than or equal to 2.1 amino acid residues, by teaching a casein hydrolysate which is 68.5% hydrolyzed (68.5% hydrolysis corresponds to an average chain length of 1.46 amino acids ($100/68.5=1.46$). The composition is treated enzymatically including with X-prolyl dipeptidyl aminopeptidase (X-PDAP) from *A. oryzae* which hydrolyzes all non-“X-Pro” bonds (e.g. methods, pages 2061-2; table 2, page 2062; Abstract).

Although Byun may be silent with respect to reciting a particular characterization of the composition or an intended use thereof, the cited reference discloses a composition comprising a

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casein hydrolysate which appears to be identical to the presently claimed composition since it was isolated from a casein composition treated with an enzyme which produces a casein hydrolysate having an average amino acid chain length of 1.46 amino acids (68.5% hydrolysis). Consequently, the claimed composition appears to be anticipated by the reference.

In the alternative, even if the composition (with respect to a disclosed concentration or proportion of amino acids or the process of making thereof) is not identical to the referenced composition, with regard to some unidentified characteristics, the differences between that which is claimed and that which is disclosed, is so slight that the referenced composition is likely to inherently possess the same characteristics of the claimed composition, particularly in view of the similar characteristics which they have been shown to share (e.g. hydrolysate of casein, enzymatic treatment to obtain the product, X-Pro linkages, etc.). Thus, the claimed composition would have been obvious to those of ordinary skill in the art within the meaning of 35 USC § 103(a).

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Since the Office does not have the facilities for examining and comparing Applicants' composition with the composition of the prior art, the burden is on applicant to show (if rejected under 35 USC § 102 or § 103) a novel or (if rejected under 35 USC § 103) unobvious difference between the claimed product and the product of the prior art. *See In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Response to Arguments

Applicants' arguments as they pertain to the art rejections above have been carefully considered but are not deemed to be persuasive of error in the rejections. Applicant has argued that Byun does not teach cleavage of Pro-Pro or bonds thereafter.

In response to Applicant's argument that Byun does not teach Pro-Pro or subsequent cleavage, this is not found to be persuasive because the composition comprises the recited components and thus may include additional elements including those taught by Byun and may include a different method of producing thereof insofar as the patentability is based on the product itself and does not depend upon its method of production. (See MPEP § 2113).

Additionally, Applicant's has argued that the X-PDP of Sanz et al is obtained from *Lactobacillus sakei*; however this is not persuasive over the prior art *Aspergillus oryzae*-obtained enzyme, where the X-PDAP of Byun appears to be identical to the disclosed enzyme based upon the features which they share (e.g. A. oryzae enzymes, 3see claim 16, table 1-example 1). Furthermore Applicant's arguments that the enzymes of Byun would not function as argued for the reasons of record is not persuasive over the prior art objective evidence which teaches "exceptionally high levels of DH [degree of hydrolysis]" including 68.5% hydrolysis (Byun see whole document including table 2; page 2063, 2nd paragraph).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. KOSAR whose telephone number is (571)270-3054. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday,EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aaron J Kosar/
Examiner, Art Unit 1651

/Christopher R. Tate/
Primary Examiner, Art Unit 1655